



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁶ : A61F 2/44</p>	<p>A1</p>	<p>(11) International Publication Number: WO 99/32055</p> <p>(43) International Publication Date: 1 July 1999 (01.07.99)</p>
<p>(21) International Application Number: PCT/US98/27476</p> <p>(22) International Filing Date: 23 December 1998 (23.12.98)</p> <p>(30) Priority Data: 60/068,660 23 December 1997 (23.12.97) US</p> <p>(71) Applicant: DEPUY ACROMED, INC. [US/US]; 3303 Carnegie Avenue, Cleveland, OH 44115 (US).</p> <p>(72) Inventors: CAMINO, Thomas, S.; 7037 Macbeth Way, Eldersburg, MD 21784-5918 (US). MALONE, John, D.; 26700 Alsace Court, No. 306, Beachwood, OH 44122 (US).</p> <p>(74) Agent: COFFEY, William, R.; Barnes & Thornburg, 11 South Meridian Street, Indianapolis, IN 46204 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>
<p>(54) Title: SPACER ASSEMBLY FOR USE IN SPINAL SURGERIES</p> <p>(57) Abstract</p> <p>A spacer assembly (100) is provided for use in spinal surgeries. Spacer assembly (100) includes a spacer (12) having opposite ends (24, 26) and a side wall (30) extending between opposite ends (24, 26) and at least one end cap (10) coupled to at least one of the opposite ends (24, 26) of spacer (10). Each end cap (10) includes an inner end (52) facing spacer (14), an outer end (50), and a side wall (54) extending between inner and outer ends (52, 50). Side wall (54) of each end cap (10) is formed for engagement with side wall (30) of spacer (12) to provide a mechanical connection between end cap (10) and spacer (12).</p> <div data-bbox="1185 1050 1461 1764"> </div>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

SPACER ASSEMBLY FOR USE IN SPINAL SURGERIESBackground and Summary of the Invention

The present application relates to spinal instrumentation systems, more particularly to spacer assemblies for use in interbody fusion procedures of the spine. Most particularly, the present invention relates to end cap caps for use with spacers that are used in spinal surgeries.

There has been a gradual acceptance of interbody fusion as a procedure for a number of spinal disorders. Interbody fusion procedures employ the use of surgical mesh tubes, see for example "Chapter 10: Titanium Surgical Mesh for Vertebral Defect Replacement and Intervertebral Spacers", Gary L. Lowery and Jürgen Harms, *Manual of Internal Fixation of the Spine*, edited by John S. Thalgott and Max Aebi, Lippincoll-Raven Publishers, Philadelphia, 1996, which is incorporated herein by reference. The surgical mesh tubes are used to reinforce weak, bony tissues in orthopaedic procedures and they act as a structural support for the spine. Moreover, a mesh pattern in the conventional surgical mesh tubes provides access for bone to grow and fuse within the tube. These surgical mesh tubes are often formed of titanium and are available in varying shapes and sizes. In addition, surgical mesh tubes can be trimmed on site by the surgeon to better provide an individual fit for each patient.

Internal rings, connector screws, and fenestrated end plates have been added to the surgical mesh tube. See, for example, "Titanium Surgical Mesh for Vertebral Defect Replacement and Intervertebral Spacers", Gary L. Lowery and Jürgen Harms, *Manual of Internal Fixation of the Spine*, edited by John S. Thalgott and Max Aebi, Lippincoll-Raven Publishers, Philadelphia, 1996. As discussed in the before mentioned article, conventional rings attach to the contoured mesh through the use of screws. The conventional rings strengthen the surgical mesh tube by acting as a reinforcement to aide in better distributing the axial loads previously taken wholly by the edge of the surgical mesh tube.

According to the present invention a spacer assembly is provided for use in spinal surgeries. The spacer assembly comprises a spacer having opposite ends and a side wall extending between the opposite ends and at least one end cap coupled

-2-

to at least one of the opposite ends of the spacer. Each end cap includes an inner end facing the spacer, an outer end, and a side wall extending between the inner and outer ends. The side wall of the end cap is formed for engagement with the side wall of the spacer to couple the end cap and spacer together.

5 In preferred embodiments, the spacer includes a passageway between the opposite ends and the inner end of the end cap extends into the passageway. The side wall of the end cap converges from the outer end toward the inner end to wedge fit the end cap in the spacer. In addition, the end cap includes at least one projection coupled to the side wall and formed to engage the spacer. The projection blocks
10 sliding movement of the end cap in the passageway of the spacer. Also, the outer end includes an outer surface that promotes bone ingrowth, such as for example a porous coating or a serrated surface. Preferably, the engagement of the end cap side wall and the projection with the side wall of the spacer 12 provides the sole mechanical connection between the end cap and the spacer.

15 Alternatively, the side wall of the end cap is formed to include a slot extending between the outer and inner ends. The slot allows the side wall of the end cap to be compressed as it is inserted into the passageway of the spacer. Once positioned in the passageway, the side wall expands toward the side wall of the spacer to friction lock the end cap in the passageway of the spacer. At least one projection
20 extends from the side wall of the compressible end cap for engagement with the spacer to block sliding movement of the end cap in the passageway.

Still further, the side wall of the spacer includes an outer surface and an alternative end cap is formed to extend over the opposite end of spacer and be coupled to the outer surface. The end cap includes an outer end, an inner end, and a side wall
25 that extends between the outer and inner ends. In addition, the side wall includes a slot extending between the outer and inner ends. The slot allows the side wall of the end cap to be expanded as it is placed about the end of the spacer. Once positioned about the outer surface of the spacer, the side wall of the end cap contracts toward the side wall of the spacer to friction lock the end cap on the side wall of the spacer. At least
30 one projection extends from the side wall of the compressible end cap for engagement with the spacer to block sliding movement of the end cap in the passageway.

Additional features of the invention will become apparent to those skilled in the art upon consideration of the following detailed description of preferred embodiments exemplifying the best mode of carrying out the invention as presently perceived.

5

Brief Description of the Drawings

Fig. 1 is a perspective view of an anterior portion of a spine, a spacer assembly in accordance with the present invention, and showing a portion of one disc removed from the spine to form a disc space and the inter-vertebral spacer sized for extension into the disc space;

10

Fig. 2 is an exploded isometric view of the spacer assembly of Fig. 1 showing the spacer assembly including a spacer and two end caps of the present invention;

Fig. 3 is a side view of the end cap of Fig. 2 showing the end cap including an outer end, an inner surface, a tapered side wall extending between the outer and inner surfaces, teeth extending outwardly from the side wall, and the outer end including a serrated surface;

15

Fig. 4 is a bottom view of the end cap of Fig. 3 showing the side wall including an outer surface and an inner surface defining a passageway and the teeth extending from the outer surface in a spaced-apart relationship relative to one another;

20

Fig. 5 is a top view of the end cap of Fig. 3 showing the serrated surface of the outer end;

Fig. 6 is an isometric view of the spacer assembly of Fig. 2 following insertion of the end caps into the spacer showing the end caps having a serrated outer side and teeth spaced apart about the periphery of the end cap and engaging the spacer to hold the end cap in place;

25

Fig. 7 is a cross-sectional view taken along the lines 7-7 of Fig. 6 showing the spacer including a cylindrical side wall defining a passageway and two end caps extending into the passageway and engaging the cylindrical side wall to wedge the end caps and spacer together;

30

Fig. 8 is a bottom view of an end cap in accordance with an alternative embodiment of the present invention showing the end cap having an oval shape;

Fig. 9 is a side view of the end cap of Fig. 8 showing the end cap having an outer end with a serrated surface, and inner end, and a tapered side wall converging from the outer end toward the inner end;

Fig. 10. is a top view of the end cap of Fig. 8 showing the serrated
5 surface;

Fig. 11 is an isometric view of the spacer of Fig. 2 and end caps in accordance with an alternative embodiment of the present invention showing the end caps having a porous coated top surface and a lip extending about the circumference of the end cap to prevent the end cap from slipping down within a passageway of the
10 surgical mesh tube;

Fig. 12 is a cross-sectional view taken along the lines 12-12 of Fig. 11 showing the tapered side wall of the end cap and the lip engaging peaks of the side wall to prevent the end caps from sliding in the passageway of the spacer;

Fig. 13 is a top view of an end cap in accordance with an alternative
15 embodiment of the present invention showing the end cap to include a solid plate formed with apertures therein;

Fig. 14 is a side view of the end cap of Fig. 13 showing the apertures, in phantom, extending between the outer and inner ends of the end plate;

Fig. 15 is a top view of an end cap in accordance with an alternative
20 embodiment of the present invention showing the end cap including a side wall having a slot formed therein and teeth coupled to the side wall;

Fig. 16 is a perspective view of the end cap of Fig. 15 showing the slot extending between the outer and inner ends of the end cap to permit compression of the end cap;

Fig. 17 is a side view of the end cap of Fig. 15 showing the side wall including a first side wall portion and a tapered second side wall portion;

Fig. 18 is a perspective view of an end cap in accordance with an alternative embodiment of the present invention showing the end cap outer and inner ends, a side wall extending between the outer and inner ends, and teeth extending
30 upwardly from the outer end and away from the side wall;

Fig. 19 is a perspective view of an end cap in accordance with an alternative embodiment of the present invention showing the end cap including a side

wall having an outer surface and an irregularly shaped inner surface defining a passageway;

Fig. 20 is a top view of the end cap of Fig. 19 showing the inner surface of the side wall defining pockets that are spaced-apart from one another;

5 Fig. 21 is a front view of the end cap of Fig. 20 showing the slot extending between the outer and inner ends;

Fig. 22 is a side view of the end cap of Fig. 20 showing the side wall including a first side wall portion and a tapered second side wall portion;

10 Fig. 23 is a perspective view of an end cap in accordance with an alternative embodiment of the present invention showing the end cap including a side wall formed without a chamfer;

Fig. 24 is a top view of the end cap of Fig. 23 showing the outer end including apertures formed therein for receiving a compression instrument;

15 Fig. 25 is a back view of the end cap of Fig. 23 showing the outer and inner end positioned to lie at an angle relative to one another;

Fig. 26 is a side view of the end cap of Fig. 23 showing the outer and inner end positioned to lie at an angle relative to one another;

20 Fig. 27 is a top view of an end cap in accordance with an alternative embodiment of the present invention showing the end cap including a crescent-shaped side wall formed for expansion from its original shape to fit over the end of the spacer;

Fig. 28 is a top perspective view of the end cap of Fig. 27 showing the side wall including an inner surface defining a passageway and a lip extending from the side wall into the passageway;

25 Fig. 29 is a bottom view of the end cap of Fig. 27 showing the lip extending into the passageway; and

Fig. 30 is a bottom perspective view of the end cap of Fig. 27.

Detailed Description of the Drawings

30 End caps 10 are provided in accordance with the present invention for use with vertebral body spacers 12 in a spine 14 during disc-replacement or vertebral body replacement surgery to form a spacer assembly 100. As shown in Fig. 1, end cap 10 is coupled to spacer 12 and is suitable for placement into an anterior portion 18 of

spine 14. This placement may be done to replace an inter-vertebral disc 20 or to replace a vertebral body 22 or multiple versions of each.

Spacer 12 is, for example, a surgical mesh tube constructed of titanium mesh. Spacer 12 houses bone (not shown) such that spacer 12 fuses to spine 14 to
 5 where there will be generally no movement between spacer 12 and spine 14 to reduce a patient's pain. Spacer 10 includes opposite ends 24, 26 and a cylindrical side wall 30 extending between ends 24, 26 and defining a passageway 32 having a predetermined inner diameter 28. Opposite ends 24, 26 each include peaks 34 and valleys 36 that form detents 38. In addition, side wall 30 has an inner surface 40, an outer surface 42,
 10 and apertures 44 extending between inner and outer surfaces 40, 42. As shown in Fig. 2, apertures 44 are generally diamond shaped and positioned to lie in a diamond-like pattern relative to one another. It is appreciated, however, that apertures 44 may have a variety of shapes and sizes and be positioned in a variety of patterns to promote bone ingrowth during the healing process. In addition to titanium mesh, end caps 10 are
 15 suitable for use with other forms of spacers that are also used in anterior portion 18 of spine 14. Specifically, end caps 10 are suitable for use with mesh spacers constructed in a variety of sizes and from a variety of metals, composites, tissue, or bone, or any other type of mesh spacer designed to be placed into spine 14 as a spinal spacer.

Referring now to Fig. 1, spine 14 includes anterior portion 18 and a
 20 posterior portion 46. In addition, spine 14 is constructed of vertebral bodies 48, seven of which are cervical vertebral bodies, twelve of which are thoracic vertebral bodies, and five of which are lumbar vertebral bodies. End caps 10 of the present invention are coupled to spacer 12 that is delivered to anterior portion 18 or posterior portion 46 of spine 14 whether it is cervical, thoracic or lumbar. Spacers 12 can be designed to
 25 replace either disc 20, as shown in Fig. 1, or vertebral body 48.

As shown in Fig. 2, end cap 10 is coupled to either end 24, 26 of spacer 12 for use in interbody fusion surgeries. End cap 10, remains at either end 24, 26 of spacer 12 without slipping down within passageway 32. As shown in Figs. 2-5, end cap 10 is formed to include an outer end 50, an inner end 52, and a tapered side wall
 30 54 converging from outer end 50 toward inner end 52. Referring now to Fig. 4, side wall 54 includes a generally cylindrical inner surface 56 having a constant diameter 58 and defining a passageway 60 and an outer surface 62. While end cap 10 is shown in

As shown in Fig. 3, outer surface 62 is further formed to include projections or interdigitating teeth 78 that are spaced apart from another adjacent to outer end 50 of end cap 10. Referring now to Figs. 6 and 7, teeth 78 are positioned on outer surface 62 such that when end cap 10 has been wedged within spacer 12, teeth 78 rest against valleys 36 of opposite ends 24, 26. Because each tooth 78 rests within detent 38, end cap 10 is thus prohibited from slipping within passageway 32 of spacer 12. The engagement of side wall 54 and teeth 78 with side wall 30 of spacer 12 provides the sole mechanical connection between end cap 10 and spacer 12. While end cap 10 is shown with seven teeth 78, it is appreciated that greater or fewer than seven teeth 78 may be coupled to outer surface 62 in accordance with the present disclosure.

DISSEM: WFO 0032055A1 1 5

Peaks 74 and valleys 76 provide a rough surface and reduce movement against vertebral body 48. Although porous and serrated outer finishes 70 are described, it is appreciated that a variety of anti-skid surfaces that promote bone ingrowth may be used in accordance with the present disclosure.

5 When replacing disc 20 or vertebral bodies 48, the surgeon first removes damaged disc 20 or bodies 48 to create a space 80. See for example disc space 80 in Fig. 1. Once space 80 is formed, the surgeon selects the appropriate size of spacer 12 and at least one corresponding end cap 10. While only one end cap 10 and end 24 of spacer 12 will be discussed hereafter it is appreciated that the description
10 and claims applies to greater than one end cap 10 and end 26. Referring now to Fig. 2, inner end 52 of end cap 10 is aligned with end 24 of spacer 12. Inner end 52 is inserted into passageway 32, as shown in Fig. 7, until outer surface 62 is wedged into engagement with side wall 30 of spacer to form a spacer assembly 100. At that time, teeth 78 will be positioned to lie within detents 38 preventing further migration of end
15 cap 10 into passageway 32 of spacer 12. Once end cap 10 is coupled to spacer 12, spacer assembly 100 may be inserted into space 80 using a variety of surgical techniques.

 In an alternative embodiment of the present invention it is provided that an end cap 110 has an oval shape. See, Figs. 8-10. End cap 110 is formed to
20 cooperate with an oval-shaped spacer (not shown) that is formed identically to spacer 12, except for the oval shape of side wall 30. End cap 110 is formed similarly to end cap 10 and like reference numerals are used to denote like components. As shown in Fig. 8, end cap 110 has a first ring width 164 adjacent to outer end 50 and a second ring width 166 adjacent to inner end 152. First ring width 164 is greater than second
25 ring width 166, so that outer surface 62 of side wall 54 converges from outer end 50 toward inner end 152 and forms about an 8 degree taper, as shown in Fig. 9. It is appreciated that the angle of taper may vary so long as end cap 110 may be wedged in spacer 12. Additionally, end cap includes ten teeth 78 coupled to outer surface 62. It is appreciated, however, that greater or fewer than ten teeth 78 may be coupled to
30 outer surface 62.

 In an alternative embodiment of the present invention, an end cap 210 is provided. End cap 210 is formed similarly to end cap 10 and like reference numerals

are used to denote like components. As shown in Figs. 11 and 12, end cap 210 includes a single projection or outer lip 282 extending from side wall 54 adjacent to outer end 50. Outer lip 282 extends about the circumference of outer end 50 and includes an inner face 284 that rests on peaks 34 of opposite ends 24, 26 respectively to prevent end cap 210 from slipping within passageway 32 of spacer 12. The engagement of side wall 54 and teeth lip 282 with side wall 30 of spacer 12 provides the sole mechanical connection between end cap 210 and spacer 12.

In still another embodiment of the present invention an end cap 310 is provided. As shown in Figs 13 and 14, end cap 310 is a solid plate 358 shown to have an oval shape and is suited particularly for use with osteoporotic bone. End cap 310 includes an outer end 350, an inner end 352, and a tapered side wall 354 converging from outer end 350 toward inner end 352. Referring now to Fig. 14, side wall 354 includes an outer surface 362. Outer surface 362 of side wall 354 is tapered similarly to outer surface 62 to form a friction lock with spacer 12. The engagement of side wall 354 with side wall 30 of spacer 12 provides the sole mechanical connection between end cap 310 and spacer 12. In addition, apertures 360 extend between outer and inner ends 350, 352. While end cap 10 is shown in Figs. 13 and 14 with generally oval outer end 350, it is appreciated that end cap 310 may be shaped similarly to end cap 10 or in a variety of shapes to cooperate with a variety of spacers 12 and/or be formed without apertures 360. It is also appreciated that end caps 10 may vary in size to cooperate with a variety of spacers 12. Further, it is appreciated that end cap 310 could be formed to include, outer teeth 54, and/or an outer lip 56.

Another embodiment of the present invention is shown in Figs. 15-17. End cap 410 includes an outer end 414, an inner end 416, and first and second side walls 420, 429 extending between outer and inner ends 414, 416. Second side wall 429 is a chamfer formed to facilitate inserting end cap 410 into spacer 12 and is tapered similarly to side wall 54 from first side wall portion 420 toward inner end 416. Second side wall 429 is shown in Fig. 15. First and second side walls 420, 429 share inside surface 418 defining passageway 422. First side wall portion 420 also includes outside surface 421 while second side wall 429 includes outside surface 423. Six teeth 454 extend around the periphery of first side wall portion 420 and are coupled outside surface 421 in the same manner as teeth 78. Teeth 454 prevent end cap 410 from

recessing too far within spacer 12. The engagement of first side wall portion 420 and teeth 454 with side wall 30 of spacer 12 provides the sole mechanical connection between end cap 410 and spacer 12. It is appreciated that the number of teeth 454 may be greater or fewer than six in accordance with the present disclosure. It is also appreciated that outer and inner ends 414, 416 may be positioned to lie generally parallel to one another or may be angled relative to one another.

As shown in Figs. 15 and 16, end cap 410 also includes inside cross-sectional ends 424, 426 so that end cap 410 has a split-ring shape. Cross-sectional ends 424, 426 define a slot or cut-out portion 428. Slot 428 allows end cap 410 to be compressed in direction 430 as it is inserted into passageway 32 of spacer 12. End cap 410 is shown in its fully opened position in Figs. 15 and 16 so that a lower outer diameter 432 (see Fig. 17) is greater than diameter 28 of passageway 32. As end cap 410 is compressed together in direction 430, it is sized for insertion within passageway 32 of spacer 12. Once inserted in spacer 12, end cap 410 expands toward its original shape and size thereby pressing against inner surface 40 of spacer 12 to insure a secure and tight fit.

Fig. 18 shows another alternate embodiment of the present invention. End cap 510 is identical to end cap 410 in nearly all respects and like reference numerals will be used to denote like components. End cap 510 includes teeth 554 coupled to outer surface 414 and extending away from side wall 420. Thus, outer end 414 is textured to provide further fixation for bone ingrowth.

As shown in Figs. 19-22, end cap 610 is provided. End cap 610 is formed similarly to end cap 410 and like reference numerals will be used to denote like components. End cap 610 is formed to include a passageway 622 extending between outer and inner ends 414, 416. Passageway 622 is irregular in shape to maximize a surface area of an inner surface 632 of first and second side walls 420, 429. As shown in Figs. 19 and 20, inner surface 632 defines pockets 634 spaced apart from one another. While end cap 610 having irregularly shaped passageway 622 with curved pockets 634 is illustrated and described, it is appreciated that end cap 610 may be formed to include a passageway having any number of shapes and sizes in accordance with the present disclosure.

-11-

Referring now to Figs. 23-26, end cap 710 is provided in accordance with the present invention. End cap 710 is formed similarly to end cap 410 and like reference numerals will be used to denote like components. End cap 710 includes a side wall 720 extending between inner and outer ends 714, 716. Side wall 720 is formed without a chamfer. In addition, as shown in Figs. 25 and 26, inner and outer ends 714, 716 are positioned to lie at a predetermined angle 731 relative to one another and are formed to include different surfaces 730, 732, such as, for example porous surface 69 and serrated surface 70. As shown in Figs. 23 and 24, end cap 710 includes apertures 734 that receive an instrument (not shown) used to compress end cap in direction 430 to be inserted into passageway 32 of spacer 12. Since side wall 720 is not tapered, the surgeon may insert either inner or outer end 714, 716 into passageway 32 so that the desired surface 69, 70 faces away from passageway 32 for engagement with vertebral body 48. It is appreciated that inner and outer ends may be positioned at a variety of angles relative to one another and may be positioned to lie in a generally parallel relationship as well in accordance with the present disclosure.

Figs. 27-30 illustrate an end cap 810 in accordance with still another embodiment of the present invention. End cap 810 fits on outer surface 42 of spacer 12 instead of within passageway 32 as previously described end caps 10, 110, 210, 310, 410, 510, 610, and 710. End cap 810 includes an outer end 814, an inner end 816, and a crescent-shaped side wall 820 extending between outer and inner ends 814, 816. It is appreciated that end cap may be formed into circular, oval, or any complex polynomial shape in accordance with the present disclosure.

Crescent-shaped side wall 820 includes an inside surface 818 defining a passageway 822 and outside surface 821. A projection or lip 854 extends about the periphery of side wall 820 adjacent to outer end 814 into passageway 822. Lip 854 prevents end cap 810 from recessing too far within spacer 12. It is appreciated that the number of lips 854 may be greater than one in accordance with the present disclosure. It is also appreciated that outer and inner ends 814, 816 may be positioned to lie generally parallel to one another or may be angled relative to one another.

As shown in Figs. 27 and 28, end cap 810 also includes inside cross-sectional ends 824, 826 defining a slot or cut-out portion 828. Slot 828 allows end cap 810 to expand in direction 830 such that inner surface 818 is sized to extend about

outer surface 42 of side wall 30 of spacer 12. Once positioned about end 24 of spacer 12, end cap 810 compresses toward its original shape and size shown in Fig. 27, thereby pressing against outer surface 42 of spacer 12 to insure a secure and tight fit. Lip 854 contacts end 24 of spacer 12 to resist axial loads. In addition, lip provides the same support as teeth 78 provide such that end cap 810 cannot recess about side wall 30 of spacer 12 toward end 26. The engagement of side wall 820 and lip 854 with side wall 30 of spacer 12 provides the sole mechanical connection between end cap 810 and spacer 12.

Therefore, end caps 10, 11, 210, 310, 410, 510, 610, 710, and 810 are formed to cooperate with spacers to form spacer assemblies for use in spinal surgeries. End caps 10, 11, 210, 310, 410, 510, 610, 710, and 810 reinforce spacers that are used in spinal and trauma surgeries to increase stability and resistance to shear forces. End caps of the present invention fit within the spacer, on the outside of the spacer, or over the spacer and are coupled to the spacer by a taper or by split-ring forces. End caps 10, 11, 210, 310, 410, 510, 610, 710, and 810 are preferably self-locking in or on spacer 12. In addition, end caps of the present invention may be formed with a variety of different polynomial shapes to fit a variety of spacer shapes and have a variety of surface coatings or textures to promote bone growth or anti-skid features to prevent movement against bone increasing stability. At least one projection extends from the end cap toward the spacer to prohibit the end cap from slipping within a passageway of the spacer body.

Although the invention has been described in detail with reference to a preferred embodiment, variations and modifications exist within the scope and spirit of the invention as described and defined in the following claims.

- ANSWER: IN W/0 003205541 1 5

11. The spacer assembly of claim 1, wherein the side wall of the spacer includes an outer surface and the side wall of the end cap is coupled to the outer surface.

12. The spacer assembly of claim 11, wherein the side wall of the end cap includes a slot extending between the outer and inner ends.

13. The spacer assembly of claim 12, wherein the side wall of the end cap defines a passageway and the end cap further includes at least one projection extending into the passageway of the side wall and engaging the spacer.

14. The spacer assembly of claim 1, wherein the side wall of the end cap includes an inner surface that defines a passageway between the inner and outer ends.

15. The spacer assembly of claim 14, wherein the inner surface of the side wall is generally cylindrical in shape.

16. The spacer assembly of claim 1, wherein the end cap is formed as a solid plate including apertures extending between the outer and inner surfaces.

17. The spacer assembly of claim 1, wherein at least one of the ends of the spacer includes peaks and valleys.

18. The spacer assembly of claim 17, wherein the end cap includes projections coupled to the side wall of the end cap and formed for extension between the peaks and engagement with the valleys of the spacer.

19. The spacer assembly of claim 17, wherein the end cap includes a projection coupled to the side wall of the end cap and formed for engagement with the peaks of the spacer.

20. A spacer assembly for use in spinal surgeries, the assembly comprising:

a spacer formed to include opposite ends and a side wall extending between the opposite ends, and

end caps coupled to the opposite ends respectively, each end caps including an inner end facing the spacer, an outer end, a side wall extending between the inner and outer ends, and at least one projection extending from the side wall, the engagement of the end cap side wall with the side wall of the spacer and the at least

one projection with the side wall with the respective opposite end of the spacer providing the sole mechanical connection between the spacer and the end caps.

21. The spacer assembly of claim 20, wherein the opposite ends are formed to include peaks and valleys.

5 22. The spacer assembly of claim 21, wherein the at least one projection engages at least one of the peaks of the respective opposite ends.

23. The spacer assembly of claim 21, wherein the at least one projection engages at least one of the valleys of the respective opposite ends.

24. The spacer assembly of claim 20, wherein the spacer includes a
10 passageway extending between the opposite ends and the inner end of the end cap
extends into the passageway.

25. The spacer assembly of claim 24, wherein the side wall of the end cap includes a slot extending between the outer and inner ends.

26. The spacer assembly of claim 24, wherein the side wall of the
15 end cap is tapered.

27. The spacer assembly of claim 20, wherein the side wall of the spacer includes an outer surface and the side wall of the end cap is coupled to the outer surface.

28. The spacer assembly of claim 27, wherein the side wall of the
20 end cap includes a slot extending between the outer and inner ends.

29. The end cap of claim 20, wherein the outer end of the end cap is generally circular in shape.

30. The end cap of claim 20, wherein the outer end of the end cap includes a coating formed to promote bone growth.

25 31. The end cap of claim 25, wherein the side wall of the end cap includes a generally cylindrical inner surface defining a passageway.

32. An end cap formed for use with a spacer having opposite ends in a spinal surgery, the end cap comprising:

an inner end, an outer end, a side wall extending between the inner and
30 outer ends, and at least one projection extending from the side wall, the side wall being
adapted to provide a mechanical connection between the end cap and the spacer to
couple the end cap and spacer together.

-16-

33. The end cap of claim 32, wherein the side wall includes an inner surface defining a passageway and an outer surface.

34. The end cap of claim 33, wherein the inner surface of the side wall is generally cylindrical in shape.

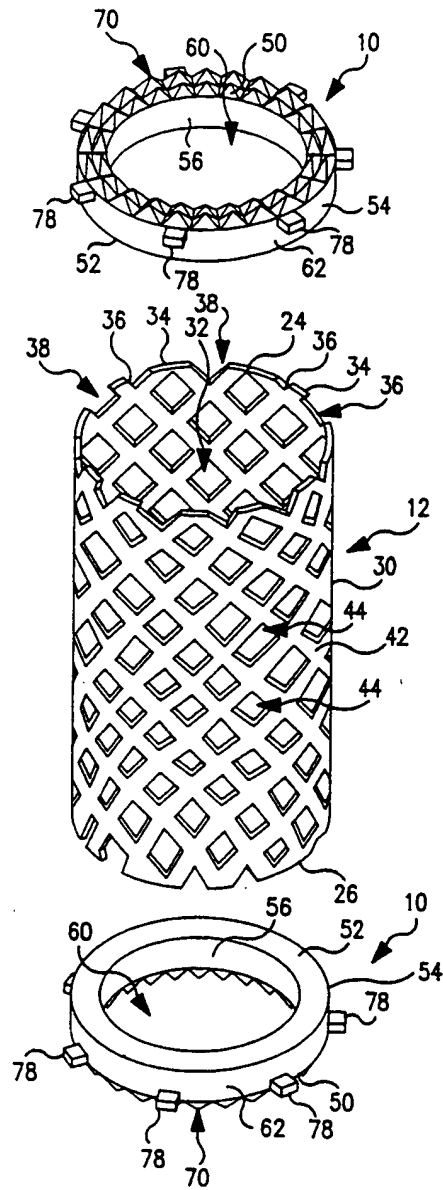


FIG. 2

SUBSTITUTE SHEET (RULE 26)

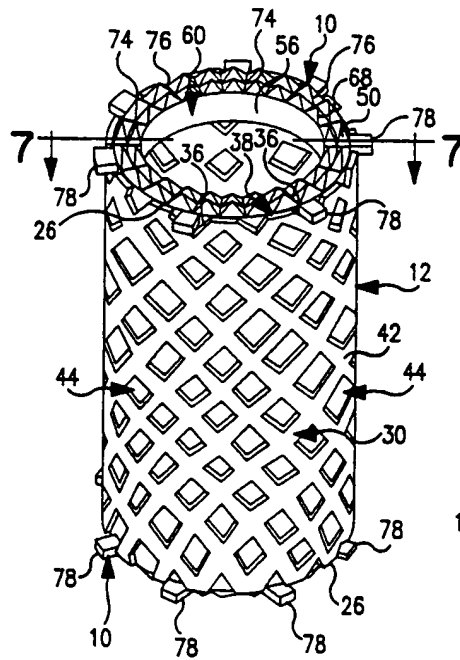


FIG. 6

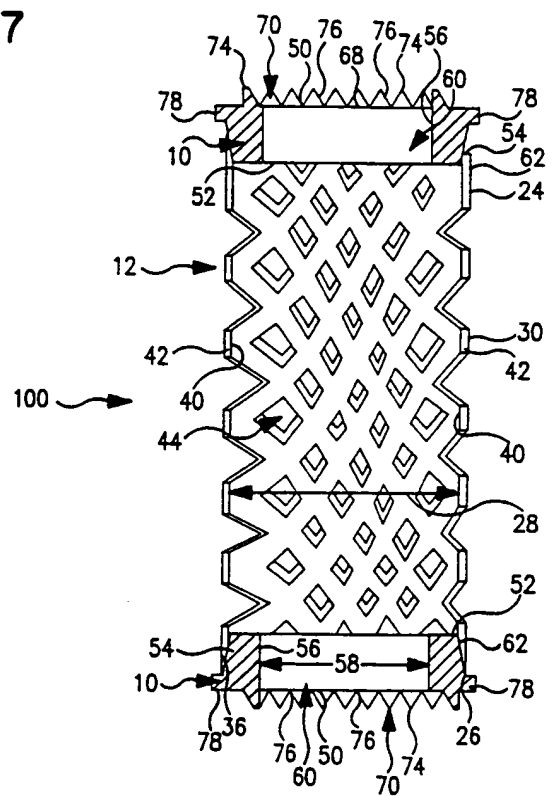


FIG. 7

SUBSTITUTE SHEET (RULE 26)

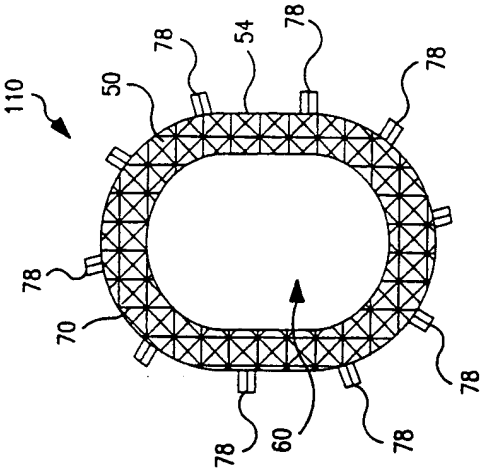


FIG. 10

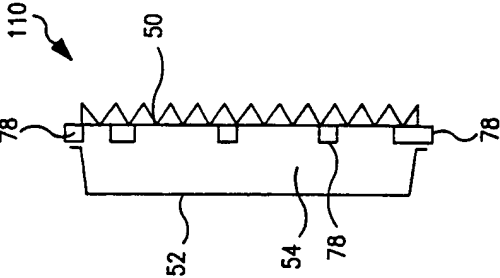


FIG. 9

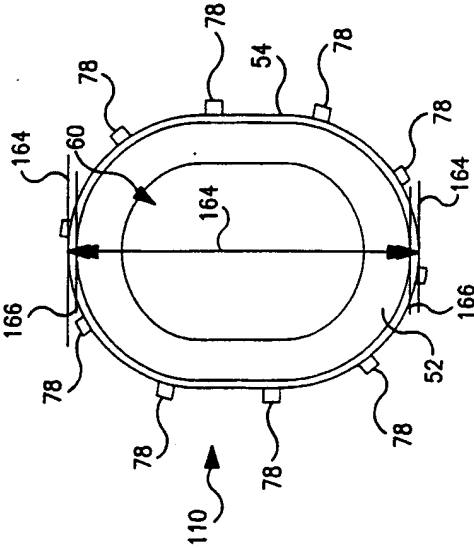


FIG. 8

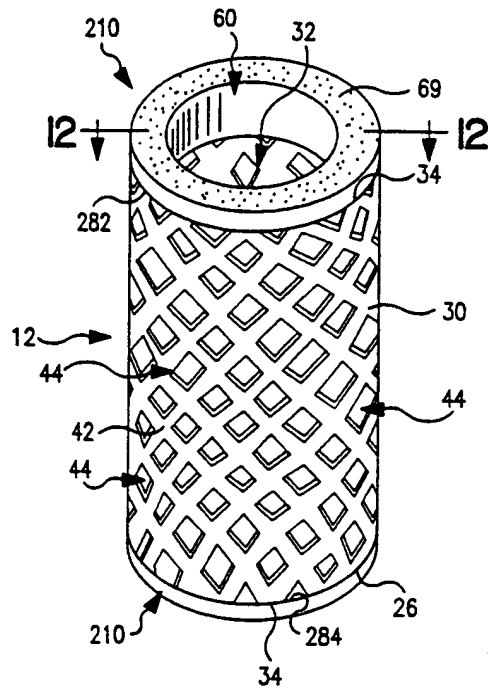


FIG. 11

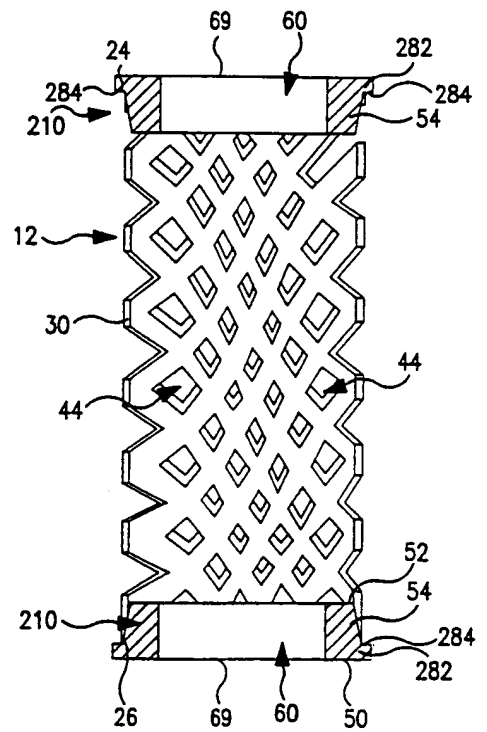


FIG. 12

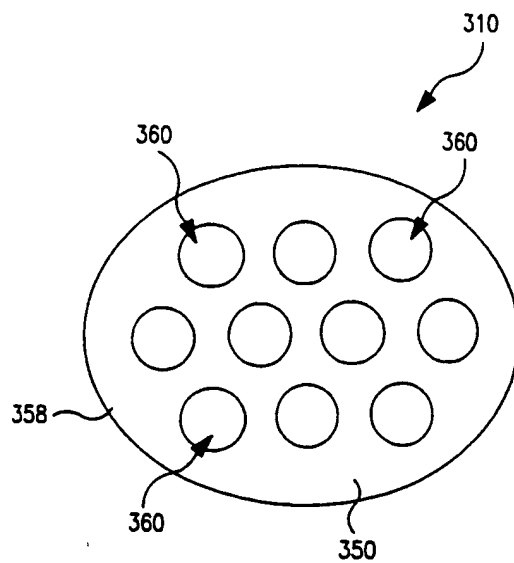


FIG. 13

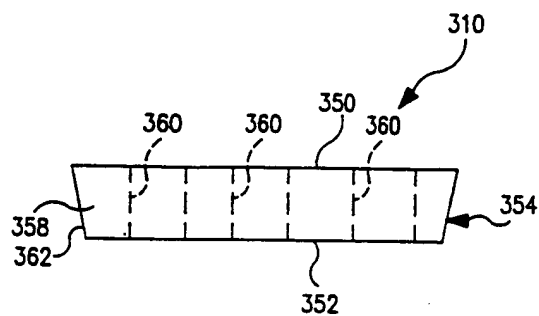


FIG. 14

SUBSTITUTE SHEET (RULE 26)

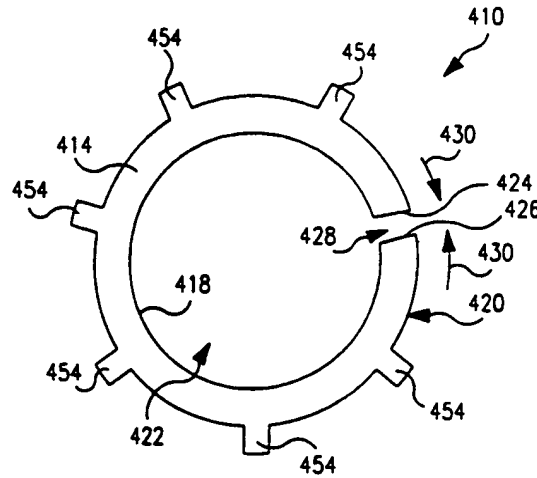


FIG. 15

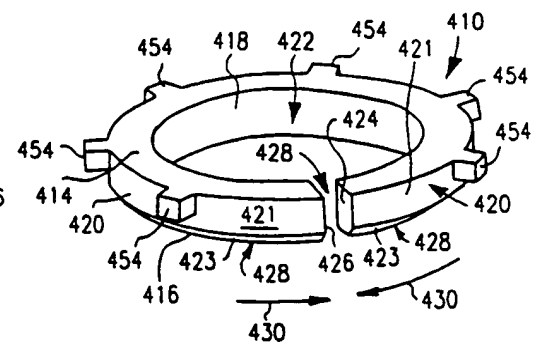


FIG. 16

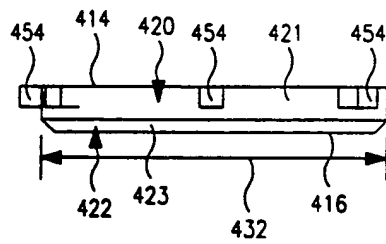


FIG. 17

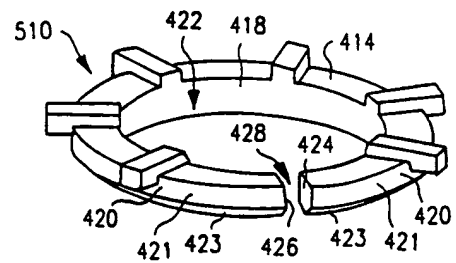


FIG. 18

SUBSTITUTE SHEET (RULE 26)

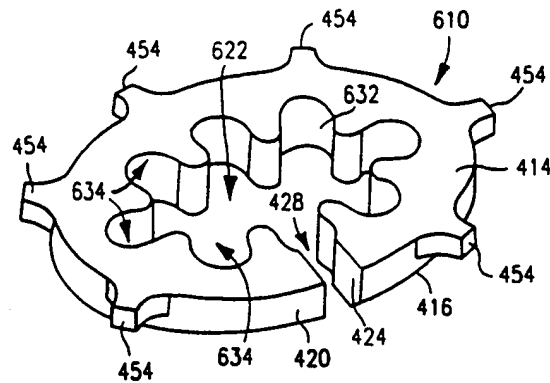


FIG. 19

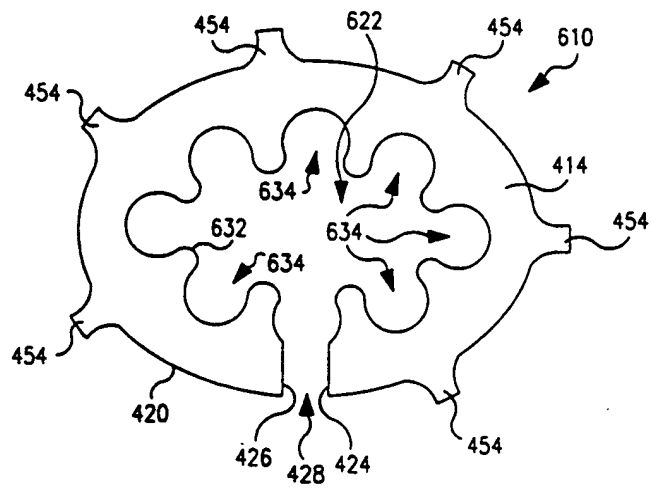


FIG. 20

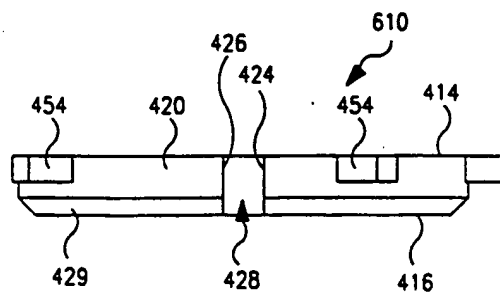


FIG. 21

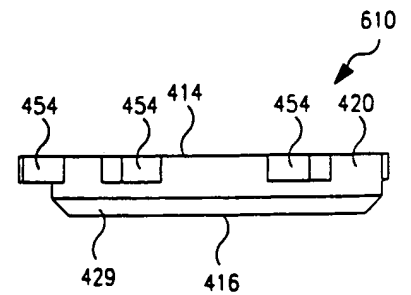


FIG. 22

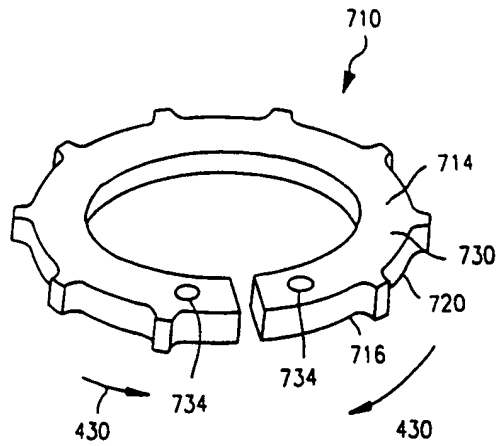


FIG. 23

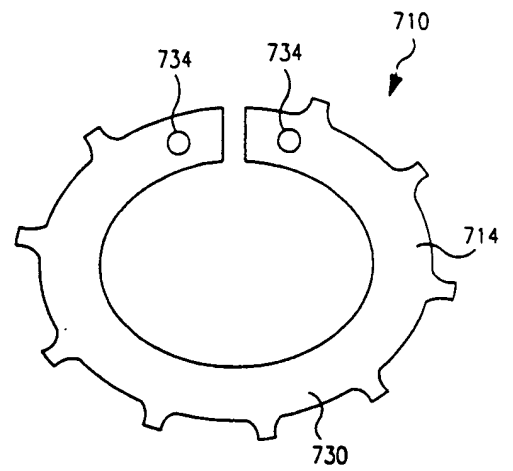


FIG. 24

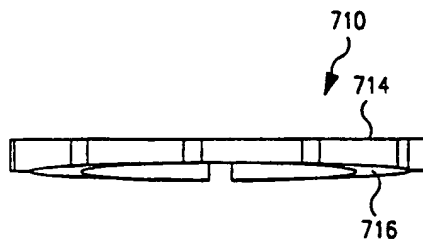


FIG. 25

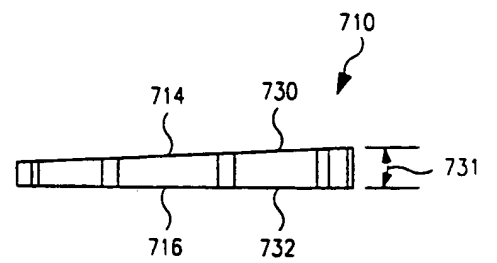


FIG. 26

SUBSTITUTE SHEET (RULE 26)

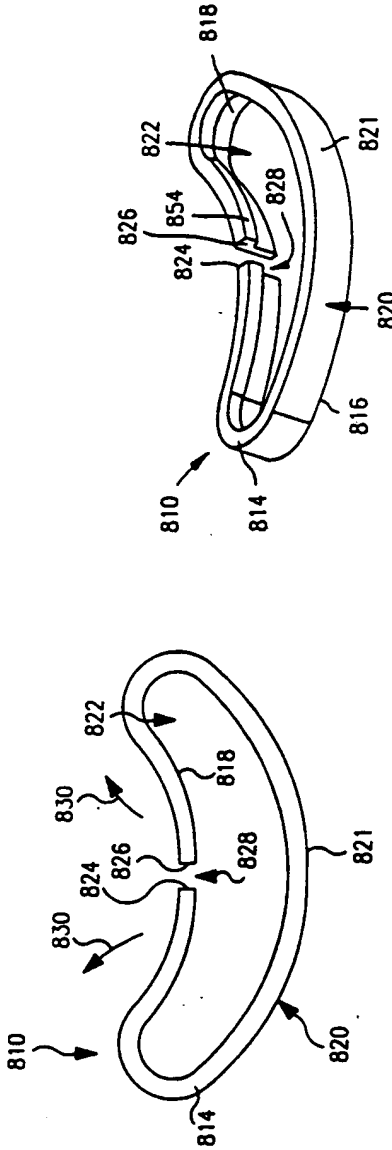


FIG. 27

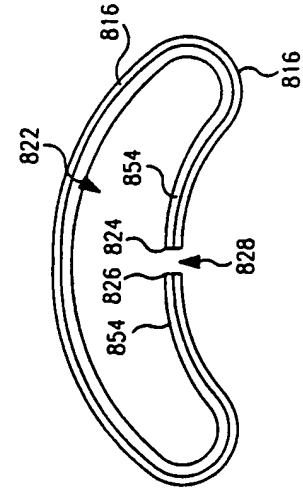


FIG. 29

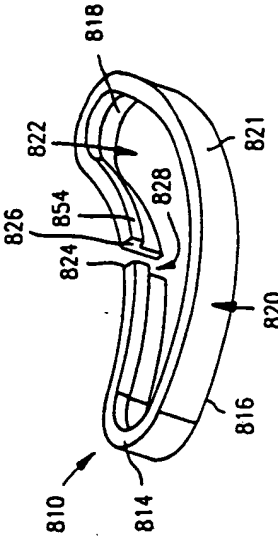


FIG. 28

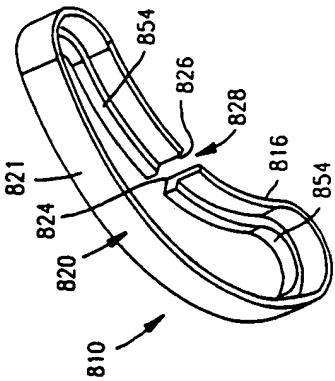


FIG. 30

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 98/27476

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 727 196 A (HARMS) 21 August 1996	1,2,7,8, 11,14, 16-24, 27,32,33
Y	see the whole document	3,4,9, 10,12, 13,15, 25,26, 28-30,34
Y	EP 0 666 068 A (SULZER MEDIZINALTECHNIK) 9 August 1995 see column 5, line 3 - line 20; figure 2	3,4,26
Y	FR 2 733 413 A (JBS) 31 October 1996	9,10,12, 13,25,28
A	see abstract; figures 1,2	6
	--- -/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

26 May 1999

Date of mailing of the international search report

08/06/1999

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Klein, C

1

Form PCT/ISA/210 (second sheet) (July 1992)

page 1 of 2

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/27476

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Y A	DE 196 22 827 A (ULRICH) 11 December 1997 see claim 5; figures 1-4 ---	15,29,34 6,31
Y A	DE 40 12 622 C (ESKA MEDICAL LÜBECK MEDIZINTECHNIK) 18 July 1991 see column 4, line 63 - line 64; figures 1,2 ---	30 5
X	EP 0 268 115 A (BIEDERMANN) 25 May 1988 see column 4, line 3 - line 17; figures 8,9 ---	1
A	EP 0 732 093 A (SOFAMOR DANEK GROUP) 18 September 1996 see column 12, line 34 - line 41; figures 8,9 ---	5,30
A	DE 195 09 317 A (ULRICH) 19 September 1996 see claims 9-12; figures 1-3,10-12 ---	6
A	DE 44 23 257 A (ULRICH) 4 January 1996 ---	
A	G.L. LOWERY & J. HARMS: "Manual of Internal Fixation of the Spine" 1996 , LIPPINCOLL-RAVEN PUBLISHERS , PHILADELPHIA XP002103821 cited in the application Chapter 10: Titanium Surgical Mesh for Vertebral Defect Replacement and Intervertebral Spacers -----	

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

page 2 of 2

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte. onal Application No

PCT/US 98/27476

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 727196	A	21-08-1996	DE 19504867 C AT 171857 T CA 2169233 A DE 59503854 D ES 2124489 T JP 8238266 A US 5702451 A	29-02-1996 15-10-1998 15-08-1996 12-11-1998 01-02-1999 17-09-1996 30-12-1997
EP 666068	A	09-08-1995	US 5645606 A	08-07-1997
FR 2733413	A	31-10-1996	DE 19615938 A JP 8299360 A US 5713899 A	31-10-1996 19-11-1996 03-02-1998
DE 19622827	A	11-12-1997	CA 2228812 A WO 9747258 A EP 0848603 A	18-12-1997 18-12-1997 24-06-1998
DE 4012622	C	18-07-1991	NONE	
EP 268115	A	25-05-1988	DE 3637314 A AT 59545 T CA 1306082 A GR 3001272 T JP 1758891 C JP 4042940 B JP 63177851 A KR 9512178 B US 4820305 A	11-05-1988 15-01-1991 11-08-1992 25-08-1992 20-05-1993 15-07-1992 22-07-1988 14-10-1995 11-04-1989
EP 732093	A	18-09-1996	US 5593409 A AU 4445196 A CA 2168835 A CN 1134810 A JP 8266563 A US 5785710 A	14-01-1997 29-08-1996 30-04-1994 06-11-1996 15-10-1996 28-07-1998
DE 19509317	A	19-09-1996	NONE	
DE 4423257	A	04-01-1996	CA 2152707 A DE 59505357 D EP 0693274 A JP 8056971 A US 5571192 A	03-01-1996 22-04-1999 24-01-1996 05-03-1996 05-11-1996

Form PCT/ISA/210 (patent family annex) (July 1992)